

REMARKS

Claims 1-26 are currently pending (claim 26 being new). Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and the following remarks. The undersigned counsel would also like to thank the Examiner for his time during the interview on September 25, 2006. The claim amendments and associated remarks comport with our discussion during the interview.

I. Specification

Paragraph 1 of the Office Action objected to the Abstract as being too long. Applicants have amended the Abstract to comport with MPEP 608.01(b) and, as such, respectfully request that this objection be withdrawn.

II. Claim Rejections

Paragraph 3 of the Office Action rejected claims 1-15 and 24-25 under 35 USC 103(a) as being unpatentable over US Pat. No. 5,474,558 to Neubardt ("Neubardt") in view of Calancie et al's article entitled "Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation" ("Calancie"). Applicants respectfully traverse this rejection as follows.

Claim 1, as amended, recites a method of determining structural integrity of a bone within the spine of a patient, where the bone has a first aspect and a second aspect, and the second aspect separated from the first aspect by a width and located adjacent to a spinal nerve. The method comprises the steps of: (a) applying an electrical stimulus to said first aspect of said bone; (b) electrically monitoring a muscle myotome associated with said spinal

nerve to *automatically* determine an onset neuro-muscular response to the application of said electrical stimulus to said first aspect of said bone; and (c) communicating to a user an *onset electrical stimulus level* which causes said onset neuro-muscular response. (Emphasis added).

While Neubardt and Calancie are certainly relevant to performing pedicle integrity assessments associated with pedicle screw placement, neither of these references appear to disclose or provide any suggestion or motivation for the claimed feature of “electrically monitoring a muscle myotome associated with said spinal nerve to *automatically* determine an onset neuro-muscular response to the application of said electrical stimulus to said first aspect of said bone,” nor the claimed feature of “communicating to a user an *onset electrical stimulus level* which causes said onset neuro-muscular response.”

As mentioned during the Examiner Interview, these distinctions are important in the success of the Applicant’s invention, which advantageously automates the process of pedicle integrity testing via the *automatic* determination of onset neuro-muscular response and communication to a user of the associated *onset electrical stimulus level* causing this onset neuro-muscular response. Pedicle screw testing has traditionally been performed by specially trained neurophysiologists who apply (or direct the application of) an electrical stimulus to the instruments used to prepare the pedicle and/or introduce the pedicle screw. Significantly, these neurophysiologists also required to interpret the resulting EMG waveforms on the associated muscle myotomes and communicate their findings to the surgeon performing the spine surgery.

One disadvantage of traditional screw testing is that the surgeon is at the mercy of the schedule of the neurophysiologist when scheduling surgeries. This is particularly troublesome for hospitals in remote areas, or in hospitals that do not have neurophysiology teams on staff, as the surgeries may have to wait for significant durations until a neurophysiologist can schedule the time to attend a particular surgery. Meanwhile, until the surgery can be scheduled around the availability of the neurophysiologist, the patient continues to suffer from the pain they seek to eliminate via the surgery. Another drawback to traditional screw testing is the added cost of having the neurophysiologist attend the case. For example, for remotely located spine surgeries, it is not uncommon for the surgeon and/or hospital to get charged for the travel costs of the neurophysiologist (e.g. mileage, airfare, hotel accommodations, etc...) in addition to the professional service fees associated with the actual surgery.

Both Neubardt and Calancie employ this traditional screw test scenario. As set forth in Neubardt, “Instead of or in addition to observing the patient 10 for leg twitching while urging the probe tip 52 into the pedicle 44, a *conventional electromyography (EMG) unit* may be connected to at least one of the leg muscles including: extensor hallicus longus, tibialis anterior, peroneals, quadriceps, and gastrocnemius.” Col. 7, lines 11-17 (Emphasis added). As expressly acknowledged on Page 3 (lines 3-5) of the Office Action, there is nothing in Neubardt that teaches or suggests the claimed feature of “electrically monitoring a muscle myotome associated with said spinal nerve to *automatically* determine an onset neuro-muscular response to the application of said electrical stimulus to said first aspect of said bone,” nor the claimed feature of “communicating to a user an *onset electrical stimulus level* which causes said onset neuro-muscular response.” Calancie does not cure these deficiencies.

Calancie describes a traditional screw test scenario, where “the electrophysiologist” (a.k.a., neurophysiologist) employs a traditional EMG system to guide a surgeon during the screw test procedure. In contradistinction to the claimed feature of “electrically monitoring a muscle myotome associated with said spinal nerve to *automatically* determine an onset neuro-muscular response to the application of said electrical stimulus to said first aspect of said bone,” in Calancie the neurophysiologist is the party determining the onset neuro-muscular response. For example, “we established the absolute threshold for evoking EMG during stimulation of the screw...” (Page 2782, Col. 1, lines 32-33), “we increased the intensity from zero only until an evoked EMG response was seen...” (Page. 2781, Col. 2, lines 13-15), and “because the technique does not use signal averaging the *decision-making process* is much more immediate...” (Page 2784, Col. 2, lines 25-26) (Emphasis added). Again, this is significantly different than the claimed feature of “electrically monitoring a muscle myotome associated with said spinal nerve to *automatically* determine an onset neuro-muscular response to the application of said electrical stimulus to said first aspect of said bone.”

Calancie similarly fails to cure the deficiency in Neurbardt regarding the claimed feature of “communicating to a user an *onset electrical stimulus level* which causes said onset neuro-muscular response.” Indeed, based on the conventional EMG system used in Calancie, it merely communicates the *EMG waveform* to the user (see Fig. 2 on Page 2782), as opposed to the onset electrical stimulus level which causes the onset neuro-muscular response (as with the present invention). For example, “The *resultant EMG* from the muscles innervated by the nerve root alerts the surgical team to a potential perforation in the pedicle” (Page 2781, Col.

1, Text describing Fig. 1) and “we increased the intensity from zero only until an evoked *EMG response* was seen...” (Page 2784, Col. 2, lines 25-26) (Emphasis added).

The present invention, in contrast, does not communicate the actual EMG waveform to the user, but rather communicates the *onset electrical stimulus level* which causes the onset neuro-muscular response. In this fashion, interpretation by a neurophysiologist is not required. Instead, the surgeon performing the spine surgery (as opposed to a neurophysiologist) can assess whether the onset electrical stimulus level causing the onset neuro-muscular response falls with the well established ranges deemed to be safe, unsafe, or of intermediate concern by simply observing the onset electrical stimulus level. This advantageously overcomes the drawbacks of having neurophysiologists perform screw test procedures (set forth above).

With these cited references being silent regarding the above-identified features of claim 1, (along with the other references of in the record), Applicants respectfully submit that one of ordinary skill in the art would not have been led to the present invention (as now claimed) after consulting with the cited references. Applicants respectfully submit that these references, whether taken alone or in combination, fail to contain the requisite teaching or suggestion that would have lead one of ordinary skill in the art to the present invention as set forth in amended claim 1. Claim 1 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

Claims 2-15 and 24-25, being dependent upon and further limiting independent claim 1, should be allowable for the reasons set forth in support of the allowability of claim 1, as well as the additional limitations they contain.

Paragraph 4 of the Office Action rejected claims 16-17 under 35 USC 103(a) as being unpatentable over Neubardt and Calancie applied to claim 14, and further in view of US Pat. No. 2,736,002 to Oriel (“Oriel”). Applicants respectfully traverse this rejection as follows.

Claim 14 depends from claim 1 and specifies that “communicating to a user includes visually indicating an intensity level of the electrical stimulus causing the onset neuro-muscular response for said spinal nerve.” As set forth above, nothing in Neubardt or Calancie teaches or suggests the claim 1 feature of “communicating to a user an *onset electrical stimulus level* which causes said onset neuro-muscular response.” The same is true of claim 14, as both Neubardt and Calancie appear to be silent regarding “visually indicating an intensity level of the electrical stimulus causing the onset neuro-muscular response for said spinal nerve.” As expressly acknowledged by the Examiner, “Neubardt...fails to disclose...communicating to a user an onset electrical stimulus level which causes the onset neuro-muscular response”(Page 3, lines 3-6). As set forth above in detail, Calancie merely displays the resulting EMG response, as opposed to the onset electrical stimulus *level* which causes the onset neuro-muscular response (as in the present invention).

Claims 16 depends from 14 and recites “visually indicating comprises illuminating lights of varying colors.” Claim 17 depends from claim 16 and recites “each color corresponds to a predetermined warning to the user.” Although Oriel does disclose illuminating lights of varying colors, where each color corresponds to a predetermined warning,” it does not cure the fundamental voids in Neubardt and Calancie as described above. More specifically, Oriel is silent regarding “visually indicating an intensity level of the electrical stimulus causing the onset neuro-muscular response for said spinal nerve.”

Based on the widely divergent subject matter between Oriel (traffic lights) and Neubardt or Calancie (pedicle screw testing), Applicants also respectfully submit that one of ordinary skill in the art would not have been lead to make the proposed combination in the first place. Even if it is combined with Neubardt and Calancie as proposed, one of ordinary skill in the art would still not have been led to the present invention given the significant voids in the teachings of Neubart, Calancie and Oriel relative to the invention as now claimed.

With Neubard, Calancie and Oriel each being silent regarding the above-identified features of claim 16 (and claim 14, from which claim 16 depends), Applicants respectfully submit that one of ordinary skill in the art would not have been led to the present invention as set forth in Claim 16 after consulting with the cited references, whether taken alone or in combination. Claim 16 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

Claim 17, being dependent upon and further limiting independent claim 16, should be allowable for the reasons set forth in support of the allowability of claim 16, as well as the additional limitations it contains.

Paragraph 5 of the Office Action rejected claims 18-23 under 35 USC 103(a) as being unpatentable over Neubardt and Calancie applied to claim 1, and further in view of US Pat. No. 5,284,153 to Raymond ("Raymond"). Applicants respectfully traverse this rejection as follows.

Claim 18 depends from claim 1 and recites "audibly indicating to an operator an intensity level of the electrical stimulus causing said onset neuro-muscular response for said

spinal nerve.” The Office Action states that “Neubardt and Calancie...fail to disclose the use of an audible indicator for indicating the intensity of the *response*” (Page 6, lines 1-3) (Emphasis added). Applicants respectfully point out that claim 18 is directed to audibly indicating an intensity level of the *electrical stimulus* causing the onset neuro-muscular response, as opposed to an intensity of the *EMG response* as characterized in the Office Action. As set forth above, this is a significant distinction between the present invention and the prior art. This void is not cured by Raymond. Nor does Raymond cure the voids in Neubardt or Calancie regarding the claim 1 feature of “communicating to a user an *onset electrical stimulus level* which causes said onset neuro-muscular response.”

With Neubard, Calancie and Raymond each being silent regarding the above-identified features of claim 18 (and claim 1, from which claim 18 depends), Applicants respectfully submit that one of ordinary skill in the art would not have been led to the present invention as set forth in Claim 18 after consulting with the cited references, whether taken alone or in combination. Claim 18 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

Claims 19-23, being dependent upon and further limiting independent claim 18, should be allowable for the reasons set forth in support of the allowability of claim 18, as well as the additional limitations they contain.

III. New Claim 26

Claim 26 depends from 14 and recites visually indicating involving the use of at least one of multi-color LEDs and an integrated display. Claim 26 does not add any new matter, but rather is fully supported via the disclosure on page 36, lines 2-4.

As noted above, neither the cited references, nor any references of record, appear to include any teaching or suggestion that would (alone or in combination) render obvious (nor anticipate) the features set forth in claim 14. Claim 14, being dependent upon and further limiting claim 14, should be allowable for the reasons set forth in support of the allowability of claim 14, as well as the additional features it contains. Applicants respectfully request that new claim 26 be allowed and an indication of such is hereby earnestly solicited.

CONCLUSION

Favorable consideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,
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